

**Amendments to the Specification:**

Kindly replace paragraphs 2-3, beginning on page 7, line 6, with the following amended paragraphs:

A stearyl macrogol glyceride that is suitable for human use and in which the fatty acid components are predominantly palmitic and stearic acids is available from Gattefosse as ~~Gelueire~~ GELUCIRE® 50/13. This is described by the manufacturer as a stearyl macrogol-32 glyceride which is synthesized by an alcoholysis/esterification reaction using hydrogenated palm oil and PEG 1500 as starting materials. It is therefore a well defined mixture of mono-, di- and triglycerides and mono- and di-fatty acid esters of polyethylene glycol. The predominant fatty acid is palmitostearic acid (C16-C18). It has a melting point in the range 46 – 51°C and an HLB value of 13.

A stearyl macrogol glyceride that is suitable for human use and in which the fatty acid components is predominantly lauric acid is available from Gattefosse as ~~Gelueire~~ GELUCIRE® 44/14. This is described by the manufacturer as a lauroyl macrogol glyceride which is synthesized by an alcoholysis/esterification reaction using hydrogenated palm oil and PEG 1500 as starting materials. It is therefore a well defined mixture of mono-, di- and triglycerides and mono- and di-fatty acid esters of polyethylene glycol. The predominant fatty acid is lauric acid (C12). It has a melting point in the range 42.5 – 47.5°C and an HLB value of 14.

Kindly replace paragraph 5, beginning on page 7, line 28, with the following amended paragraph:

A fatty acid glyceride mixture with suitable properties is ~~Gelueire~~ GELUCIRE® 50/02 from Gattefosse which has an average melting point of 50°C and an HLB value of 2. Another fatty acid glyceride mixture with suitable properties is ~~Preirol~~ PRECIROL® ATO 5, also from Gattefosse, which has an average melting point of 55°C and an HLB value of 2. It is synthesized by esterification of glycerol by palmitostearic acid (C16-C18 fatty acid). The raw materials used are of strictly vegetable origin and the reaction process involves no catalyst.

The manufacturer indicates that ~~Preeirol~~ PRECIROL® ATO 5 is composed of mono-, di and triglycerides of palmitostearic acid, the diester fraction being predominant.

Kindly replace paragraph 1, beginning on page 8, line 1, with the following amended paragraph:

An advantage of the blended carrier is that the proportions of the components can be varied to change the release profile of the carrier i.e. the rate of release can be reduced by increasing the amount of the more hydrophobic component (the component with the lower HLB value). For example, a suitable carrier may be prepared by blending ~~Gelueire~~ GELUCIRE® 50/13 and ~~Preeirol~~ PRECIROL® ATO 5 in proportions ranging from 40 to 70% of ~~Preeirol~~ PRECIROL® ATO5.

Kindly replace Table 1, beginning on page 8, line 12, with the following amended table:

Table 1: Effect of ~~Preeirol~~ PRECIROL® ATO5 concentration and tablet weight on dissolution profile

| Dissolution Timepoint<br>(Hours) | 50% <del>Preeirol</del> <u>PRECIROL®</u><br>ATO5 –<br>269 mg tablet weight | 60% <del>Preeirol</del> <u>PRECIROL®</u><br>ATO5 –<br>400 mg tablet weight |
|----------------------------------|--|--|
| 1                                | 18   | 15   |
| 2                                | 28   | 24   |
| 4                                | 41   | 36   |
| 6                                | 47   | 39   |
| 8                                | 52   | 42   |
| 10                               | 58   | 44   |
| 12                               | 64   | 47   |
| 16                               | 70   | 54   |

Kindly replace paragraph 7, beginning on page 14, line 25, with the following amended paragraph:

~~Gelucire~~ GELUCIRE® 50/13 (Gattefosse) and ~~Precirol~~ PRECIROL® ATO5 (Gattefosse) were melt blended at 70 °C. The temperature of the blend was allowed to decrease to between 52 and 57°C. Compound (A) as the maleate (GlaxoSmithKline) was added to the molten blend, so that the resultant mixture contained the three components in the proportions

|  | % w/w |
|--|-------|
| Compound (A) Maleate                             | 4     |
| <del>Gelucire</del> <u>GELUCIRE®</u> 50/13 (wax) | 46    |
| <del>Precirol</del> <u>PRECIROL®</u> ATO5 (wax)  | 50    |

Kindly replace paragraph 2, beginning on page 15, line 6, with the following amended paragraph:

~~Gelucire~~ GELUCIRE® 50/13 (Gattefosse) and ~~Precirol~~ PRECIROL® ATO5 (Gattefosse) were melt blended at 70 °C. The temperature of the blend was allowed to decrease to between 52 and 57°C. Compound (A) Maleate (GlaxoSmithKline) was added to the molten blend, so that the resultant mixture contained the three components in the proportions

|  | % w/w |
|--|-------|
| Compound (A) Maleate                             | 2.65  |
| <del>Gelucire</del> <u>GELUCIRE®</u> 50/13 (wax) | 37.35 |
| <del>Precirol</del> <u>PRECIROL®</u> ATO5 (wax)  | 60    |

Kindly replace paragraph 7, beginning on page 15, line 25, with the following amended paragraph:

~~Gelucire~~ GELUCIRE® 50/13 (Gattefosse) and ~~Precirol~~ PRECIROL® ATO5 (Gattefosse) were melt blended at 70 °C. The temperature of the blend was allowed to decrease to between 55 and 60°C. Compound (A) Maleate (GlaxoSmithKline) was added to the molten blend, so that the resultant mixture contained the three components in the proportions

|  | % w/w |
|--|-------|
| Compound (A) Maleate                             | 4     |
| <del>Gelucire</del> <u>GELUCIRE®</u> 50/13 (wax) | 46    |
| <del>Precirol</del> <u>PRECIROL®</u> ATO5 (wax)  | 50    |

Kindly replace paragraph 1, beginning on page 16, line 3, with the following amended paragraph:

Dissolution rates for the formulations of Examples 1 and 2 were measured starting at pH 1.5 with an adjustment to pH 6.8 after 4 hours, as an assumed time for residence in the fed stomach before emptying into the intestines. The medium for this dissolution test is initially an aqueous solution of sodium chloride and hydrochloric acid, pH 1.5 to mimic the pH found in the stomach environment. This medium is then titrated to pH 6.8 by the addition of aqueous sodium dodecyl sulfate and an aqueous solution of sodium acetate and tris(hydroxymethyl)methylamine after 4 hours to mimic the pH found in the intestine. The results are plotted in Figure 1. The formulation of Example 2 gave a slower release of rosiglitazone than the tablet of Example 1, by virtue of the increased amount of ~~Precirol~~ PRECIROL® ATO 5, giving a more hydrophobic character to the matrix, and because of the increased tablet size.